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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,877	05/11/2006	Jean-Claude Maurel	67987.000003	5038

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EXAMINER	
LAU, JONATHAN S	
ART UNIT	**PAPER NUMBER**
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,877	MAUREL ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11,13-15 and 17-21* is/are pending in the application.

4a) Of the above claim(s) *17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,13-15 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 23 May 2008, in which claims 7, 14 and 15 are amended; and claims 10 and 16 are canceled.

This application is the national stage entry of PCT/FR04/02912, filed 15 Nov 2004; and claims benefit of foreign priority document FRANCE 0313357, filed 14 Nov 2003.

Claims 1-9, 11, 13-15 and 17-21 are pending in the current application. Claims 17-20, drawn to non-elected inventions, are withdrawn.

Rejections Withdrawn

Applicant's Amendment, filed 23 May 2008, with respect to claims 7 and 14 rejected under 35 USC 112, first paragraph as containing subject matter which was not described in the specification has been fully considered and is persuasive, as amended claims 7 and 14 recite subject matter that is described in the specification as filed.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 23 May 2008, with respect to claims 10 rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement has been fully considered and is persuasive, as claim 10 is canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 23 May 2008, with respect to claims 7 and 14-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite has been fully considered and is persuasive, as the claims as amended recite the term "strontium cation" used according to its ordinary meaning, the term "dihalogenide" is deleted, and claim 16 is canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 23 May 2008, with respect to claims 1-11, 13-16 and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Maurel et al. (US Patent 6,129,924, issued 10 Oct 2000, of record), herein referred to as the '924 Patent, in view of Henquin (Pflugers Archive - European Journal of Physiology, 1980, 383, p123-129, of record) has been fully considered and is persuasive with regards to claims 10 and 16 as claims 10 and 16 are canceled.

This rejection of claims 10 and 16 has been **withdrawn**.

The following new or modified grounds of rejections are necessitated by Applicant's Amendment, filed 23 May 2008, in which claims 7, 14 and 15 are amended; and claims 10 and 16 are canceled

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

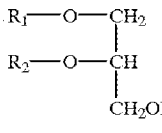
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claims 1-9, 11, 13-15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maurel et al. (US Patent 6,129,924, issued 10 Oct 2000, of record), herein referred to as the '924 Patent, in view of Henquin (Pflugers Archive - European Journal of Physiology, 1980, 383, p123-129, of record).

The '924 Patent discloses organometallic complexes obtainable by the reaction of a cation of metal in the +2 oxidation state useful as a biocatalyst in living metabolism, sitosterol or a plant extract containing sitosterol, and a diglyceride of formula



where R_1 is oleic acid and R_2 is an oleyl or acetyl group (column 5, lines 13-35), addressing instant claims 1-6, 13 and 21. The '924 Patent discloses the acylgycerol is obtained by isolation from olive oil (column 7, lines 65-67), addressing the product-by-process of instant claim 6. The '924 Patent discloses metal cation in the

form of halides, sulphates, hydrates, acetylacetonates, alkoxides (or alcoholates) or complexes with organic solvents (column 6, lines 9-15), addressing instant claims 7 and 14-16. Instant claim 16 as disclosed claims,

> "Organometallic complexes produced by the process comprising reacting:
> at least one strontium cation,
> sitosterol or a plant extract containing same,
> at least one mono-, one di- or one triglyceride corresponding to formula (I): in which: R_1 is an acyl moiety of a C14 to C24 fatty acid, saturated or not, linear or branched, a hydrogen atom, or a mono-, di- or tri-galactose or glucose, R_2 is an acyl moiety of a C2 to C 18 fatty acid, linear or branched, saturated or not, R_3 is an acyl moiety of a C14 to C24 fatty acid, saturated or not, linear or branched, or a hydrogen atom,
> **in which the strontium cation is a dihalogenide, an organic strontium derivative or a complex of strontium with organic solvents,**
> wherein the organic strontium derivative is an acetylacetonate or an alcoholate,
> wherein the organic strontium derivative is strontium ranelate."

Instant claim 16 does not require that the strontium cation is an organic strontium derivative. Therefore an organometallic complex in which the metal cation is the dihalogenide in the form of a metal halide addresses instant claim 16. The '924 Patent discloses pharmaceutical compositions comprising said organometallic complex and a pharmaceutically acceptable vehicle, excipient, or carrier (column 10, lines 16-19), addressing instant claim 8. The '924 Patent discloses preparation of a medicine of said organometallic complex such as said pharmaceutical composition (column 10, lines 47-49), addressing instant claims 9 and 10. The '924 Patent discloses "A method for preparing a medicament comprising combining the complexes of claim 1 with a pharmaceutically acceptable vehicle, excipient or support", therefore the disclosed invention addresses all structural limitations of instant claims 9 and 10. See MPEP 2111.02 II. The '924 Patent discloses dietary products that contain said organometallic complex (column 11, lines 11-12), addressing instant claim 11. The '924 Patent discloses the organometallic complex useful as a product with anti-diabetic and/or

insulinomimetic activity and that the choice of the metal cation will be based on the desired activity (column 5, lines 44-48).

The '924 Patent does not disclose the specific cation of metal in the +2 oxidation state, strontium.

Henquin teaches that strontium ions in the +2 oxidation state supports glucose-stimulated insulin release (page 127, right column, lines 27-29). Henquin teaches Sr^{2+} is active in the insulin releasing process but does not have the same efficiency as Ca^{2+} (page 128, right column, lines 41-48).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the cation of metal in the +2 oxidation state of the organometallic complexes disclosed in the '924 Patent with strontium ions in the +2 oxidation state taught by Henquin. Both the the organometallic complexes disclosed in the '924 Patent and strontium ions in the +2 oxidation state taught by Henquin have anti-diabetic and/or insulinomimetic activity. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute equivalents known for the same purpose. See MPEP 2144.06. The fact that Henquin teaches Sr^{2+} does not have the same insulin releasing efficiency as Ca^{2+} does not consititute teaching away from the broader disclosure of Sr^{2+} as a cation of metal in the +2 oxidation state with anti-diabetic and/or insulinomimetic activity. See MPEP 2123 II.

Claims 1-11, 13-16 recite a product-by-process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its

method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Response to Applicant's Remarks:

Applicant's Remarks, filed 23 May 2008, have been fully considered and not found to be persuasive.

Applicant remarks that there is no recognition of equivalency in the prior art. Applicant asserts that Henquin does not recognize the equivalency of Sr^{2+} as usefully in forming organometallic complexes having a particular activity. However, Maurel et al. teaches the requirements for the cation of a metal (M) is those that have an oxidation state at least equal to 2 useful as a biocatalyst in living metabolism (column 4, lines 10-15). Henquin teaches the divalent cation Sr^{2+} playing a role in stimulation of insulin release (page 123, left column paragraph 1 and right column paragraphs 1-2), a cation of a metal (M) is those that have an oxidation state at least equal to 2 useful as a

biocatalyst in living metabolism. Applicant remarks that the Office Action mailed 23 Jan 2008 does not provide support for the assertion that Henquin teaches Sr^{2+} has anti-diabetic activity. While Henquin does not describe the stimulation of insulin release by Sr^{2+} using the specific description of anti-diabetic activity, it is well-known in that art stimulating insulin release using insulin secretagogues is one approach to the treatment of diabetes. See definition of Diabetes Mellitus (Merck Manual Home Edition, cited in PTO-892), page 9, paragraph 1 of Oral Antihyperglycemic Drugs. Therefore it is implicit from what is taught by Henquin that Sr^{2+} has anti-diabetic activity.

Applicant asserts that the '924 patent teaches away from using Strontium. However, the preferred embodiments disclosed in the '924 patent, such as the non-limiting exemplary embodiments of vanadium, niobium, molybdenum, selenium, chromium, or zinc (column 5, lines 45-50), do not constitute teaching away from the broader teaching of the use of **any** cation of a metal (M) is those that have an oxidation state at least equal to 2 useful as a biocatalyst in living metabolism (column 5, lines 35-40). See MPEP 2123 II. The '924 patent also teaches the use of not only transition metals or non-metals, but also the alkali metal lithium (column 6, line 5) and preparation of the complex using alkali earth metals (column 6, lines 10-15).

Applicant asserts there is no reason to combine. As recited above, the prior art teaches Sr^{2+} as an equivalent cation of a metal (M) is those that have an oxidation state at least equal to 2 useful as a biocatalyst in living metabolism and implicitly teaches the anti-diabetic activity of Sr^{2+}. An express suggestion to substitute one equivalent

component or process for another is not necessary to render such substitution obvious, see MPEP 2144.06 II.

Applicant remarks that there is no reasonable expectation of success in using the strontium for treating diabetes. As recited above, the prior art implicitly teaches the anti-diabetic activity of Sr^{2+}. The '924 patent teaches preparation of the complex using alkali earth metals (column 6, lines 10-15). Therefore one of ordinary skill in the art would have a reasonable expectation of success in preparing a complex according to the '924 patent using Sr^{2+} having the biocatalytic activity that is implicitly anti-diabetic activity taught by Henquin.

Conclusion

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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